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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,333	03/31/2004	Carsten Rosenow	3334.3	7530

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EXAMINER	
ZHOU, SHUBO	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/815,333	ROSENOW ET AL.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The preliminary amendments to the specification and claims filed 3/3/1/04 are acknowledged and entered. Claims 10-14 are currently pending and under consideration.

Specification

The specification is objected to because of the following:

Trademarks are used in this application, such as GENECHIP on page 7. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections-35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 10-14 are drawn to computer software product comprising computer program codes and computer readable medium for storing the codes.

Since "computer readable medium" is defined in the specification page 6, line 18, as including "a data signal embodied in a carrier wave," at least one embodiment of the claimed invention is drawn to data signal embodied in a carrier wave with program codes.

It was held by the court that claims that recite nothing but the physical characteristics of a form of energy, such as a frequency, voltage, or the strength of a magnetic field, define energy or magnetism, per se, and as such, are nonstatutory natural phenomena. O'Reilly, 56 U.S. (15 How.) at 112-14. Moreover, it does not appear that a claim reciting a signal encoded with functional descriptive material, e.g. a computer program, falls within any of the categories of patentable subject matter set forth in § 101. The following analysis on why such a signal encoded with functional descriptive material is nonstatutory subject matter is excerpted from the US PTO's "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm):

First, a claimed signal is clearly not a "process" under § 101 because it is not a series of steps. The other three § 101 classes of machine, compositions of matter and manufactures "relate to structural entities and can be grouped as 'product' claims in order to contrast them with process claims." 1 D. Chisum, Patents §1.02 (1994. The three product classes have traditionally required physical structure or material.

"The term machine includes every mechanical device or combination of mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result." Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1854). A modern definition of machine would no doubt include electronic devices which perform functions. Indeed, devices such as flip-flops and computers are referred to in computer science as sequential machines. A claimed signal has no physical structure, does not itself perform any useful, concrete and tangible result and, thus, does not fit within the definition of a machine.

A "composition of matter" "covers all compositions of two or more substances and includes all composite articles, whether they be results of chemical union, or of mechanical

mixture, or whether they be gases, fluids, powders or solids." Shell Development Co. v. Watson, 149 F. Supp. 279, 280, 113 USPQ 265, 266 (D.D.C. 1957), aff'd, 252 F.2d 861, 116 USPQ 428 (D.C. Cir. 1958). A claimed signal is not matter, but a form of energy, and therefore is not a composition of matter.

The Supreme Court has read the term "manufacture" in accordance with its dictionary definition to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery." Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, 196-97 (1980) (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11, 8 USPQ 131, 133 (1931), which, in turn, quotes the Century Dictionary). Other courts have applied similar definitions. See American Disappearing Bed Co. v. Arnaelsteen, 182 F. 324, 325 (9th Cir. 1910), cert. denied, 220 U.S. 622 (1911). These definitions require physical substance, which a claimed signal does not have. Congress can be presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change. Lorillard v. Pons, 434 U.S. 575, 580 (1978). Thus, Congress must be presumed to have been aware of the interpretation of manufacture in American Fruit Growers when it passed the 1952 Patent Act.

A manufacture is also defined as the residual class of product. 1 Chisum, § 1.02[3] (citing W. Robinson, The Law of Patents for Useful Inventions 270 (1890)). A product is a tangible physical article or object, some form of matter, which a signal is not. That the other two product classes, machine and composition of matter, require physical matter is evidence that a manufacture was also intended to require physical matter. A signal, a form of energy, does not fall within either of the two definitions of manufacture. Thus, a signal does not fall within one of the four statutory classes of § 101.

[.....]

These interim guidelines propose that such signal claims are ineligible for patent protection because they do not fall within any of the four statutory classes of § 101. Public comment is sought for further evaluation of this question.

Thus, claims 10-14 are drawn to nonstatutory subject matter.

Claim Rejections-35 USC §112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites "... code that receives ..." and "... code that identifies ...." The limitations are confusing because it is not clear how a code receives data and identifier a region of a genome. Ditto for claim 11 where it is recited "... code that identifiers an area of said genome...."

Claim 12 recites "the difference in said intensities for said probes against said area is within 2 fold." The metes and bounds of the limitation are not clear. It is not clear what difference is referred to. The phrase "the difference in said intensities for said probes against said area" could be interpreted as the difference between the highest intensity generated by a probe of the probes against the area and the lowest intensity generated by a probe of the probes against the area. Or it could be interpreted as the difference between the intensities of any two probes of the plurality of probes. Claim 13 is rejected for the same reasons. Claim 14 is rejected because of being dependent from claim 11.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leary et al. (WO 99/67422, 29 December 1999) in view of Lockhart et al. (WO 97/10365, 20 March 1997).

The claims are drawn to a computer software product a computer readable medium and computer program code for receiving a plurality of hybridization intensities of a plurality of probes against a region of a genome, code for identifying a region so the genome wherein intensities for said probes against the regions are above a threshold values.

Leary et al. disclose a method for mapping the position of individual transcripts from a genome comprising hybridizing a plurality of nucleic acid probes with a nucleic acid sample wherein the sample comprises transcripts from the genome and the probes are from an area of the genome (page 4, first paragraph) and such probes are immobilized to a substrate (pages 7-8, the bridging paragraph).

Leary et al. do not explicitly recite a threshold value for the hybridization signal of a region, above which, the region would be considered as transcribed.

Lockhart et al. teach a method of monitoring gene expression by hybridization of transcripts to high density oligonucleotide arrays. The method comprises hybridizing test transcripts to genomic probes immobilized onto substrates (page 3, Summary of the invention).

To reduce the signal/noise ratio, Lockhart et al. teach using different control probes including normalization controls, expression level controls and mismatch control (pages 6-7 and 34-35).

Lockhart et al. state (page 39):

> The oligonucleotide array is hybridized to a sample containing target nucleic acids having subsequences complementary to the oligonucleotide probes and the difference in hybridization intensity between each probe and its mismatch control is determined. Only those probes where the difference between the probe and its mismatch control exceeds a threshold hybridization intensity (e.g. preferably greater than 10% of the background signal intensity, more preferably greater than 20% of the background signal intensity and most preferably greater than 50% of the background signal intensity are selected.

A person having ordinary skill in the art at the time the invention was made would, therefore, have been motivated by Lockhart et al. to modify Leary et al. to include all the control probes including the mismatch probes and to use a threshold with each control probe as suggested by Lockhart et al. in order reduce the signal/noise ratio. It would have been obvious that once the hybridization signals in Leary et al. would have been deemed authentic (i.e. not noise), since the hybridization were between transcripts and genomic DNAs with known regions, it would have been apparent that those regions represented by the probes are transcribed regions.

Neither Leary et al. nor Lockhart et al. explicitly teach computer program codes for the process of the method.

In *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure,* U.S. Trademark and Patent Office, section 2144.04, III).

In the instant case, the computer software product is for automating the process. It is thus not sufficient to distinguish over the method process of the combination of Leary et al. and Lockhart et al. Therefore, the claimed invention, i.e. the computer software product comprising computer codes and computer readable medium would have been obvious to a person of ordinary skill in the art at the time the invention was made over Leary et al. and Lockhart et al.

Furthermore, Lockhart et al. disclose computer systems and software for accepting the signal intensities of the probes and processing the signals using statistical analysis, etc. See at least pages 88-93. One having ordinary skill in the art would have been motivated by Lockhart et al. to use a computer system with computer software for processing the hybridization intensities of the signals in order to fully automate the process, save time and cost and increase accuracy of the analysis.

There would have been a reasonable expectation of success because the court held regarding software that "writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed." Fonar Corp., 107 F.3d at 1549, 41 USPQ2d at 1805.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D. 9/26/05
Patent Examiner